quality to be detected can comprise numerous indicia including cell size, cell shape, nuclear size, nuclear shape, as well as biological and chemical markers (see specification pages 7-8). The means to detect such diverse indicia includes, but is not limited to, biochemical, mechanical, electrical, and microelectromechanical (MEMS), all of which would be well know to a person of ordinary skill in the art. For the reasons stated above, Applicant respectfully requests that the Examiner reconsider and withdraw the objection.

The Rejection Under 35 U.S.C. § 102 (a) Should Be Withdrawn

In the Office Action, claims 1-6 were rejected under 35 USC §102(b) as being unpatentable with respect to U.S. Pat. No. 5,623,942 to Pestes *et al.*

However, as discussed below, the device recited in the pending claims is not anticipated by the patent to Pestes *et al.* The patent to Pestes *et al.* discloses a swab for collecting cell samples from a male urethra. The swab includes a unitary elongate shaft having a constant diameter cylindrical handle at one end and a tapered circular cross-sectioned probe at the other end.

In the Office Action, it is asserted that the Patent to Pestes *et al.* discloses a flexible probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis. However, no such description appears in the Patent to Pestes *et al.*

The Patent to Pestes *et al.* does not contemplate a method or device other than for the collection of cell samples from a male urethra. Further, the device depicted in the disclosure is sized for accessing the urethra. The urethra is significantly larger than the orifice of a breast duct. It is known to those skilled in the art that a single nipple contains at least eight or more ductal orifices that open into respective breast ducts. As the examiner points out in the Office

Action (see page 3), Pestes *et al.* discloses a probe with a diameter of **0.08 cm** (emphasis added). The device of the present invention has a diameter sufficiently small to penetrate a breast duct, or about from 0.008 cm to about 0.040 cm (see specification page 6). Thus, the Patent to Pestes *et al.* describes an invention that is almost twice the maximum diameter of the device of the present invention. Further, it is well known to those skilled in the art that magnification or vision enhancing devices are commonly used to locate a ductal orifice on a nipple surface, whereas the urethra is clearly visible to the human eye. The size considerations for accessing a male urethra are significantly different from those of a breast duct.

Therefore, contrary to the position taken in the Office Action, the Patent to Pestes *et al.* does not disclose a probe having a diameter sized to penetrate a breast duct, rather it discloses only a much larger device for insertion into an urethra. As a result, the Applicant asserts that a prima facie case of anticipation has not been set forth because the device disclosed in the Patent to Pestes *et al.* is not sized to penetrate a breast duct through a ductal orifice, pass through the sphincter, contact an interior lumen of a breast duct, and retrieve a sample of the breast duct fluid. Further, the examiner has provided no motivation to combine the disclosed device with other art or to significantly reduce the size of the device as the device was only depicted and disclosed to access a male urethra. Additionally, one of ordinary skill in the art would not have been motivated to reduce the size of the swab so that it could fit in a breast duct because the possibility of puncturing the duct and significantly injuring the patient would exist. A person of ordinary skill in the art would recognize the serious potential for injury of a patient by placing a swab of the diameter described in the Patent to Pestes *et al.*, in a breast duct of a body.

For all of the above discussed reasons, the Patent to Pestes *et al.* does not disclose the recited device. Additionally, it would not have been obvious to one of ordinary skill in the art to modify the swab of Pestes *et al.* so that it could receive a ductal fluid sample because no

motivation exists for such a modification and such a modification is contrary to the common knowledge of the ordinary artisan.

The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 7-8, 26 and 27 were rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 5,623,942 to Pestes *et al.* in view of U.S. Pat. No. 4,616,656 to Nicholson *et al.*

The patent to Nicholson *et al.* discloses a device and method for confirming the location of a presymptomatic, non-palpable breast lesion by placement and manipulation of a probe. The probe is comprised of a cannula housing a wire. The wire is percutaneously introduced into the fleshy sidewall of a breast whereat it is hoped the distal end lies at about 2 cm from a lesion previously determined by a mammography. The percutaneously inserted probe wire remains as a location marker for invasive surgical excision of the lesion. Also, the percutaneously inserted wire is coated with a silicone or Teflon for purposes of lubricity and electrical insulation.

Both silicone and Teflon, which are disclosed as coatings on the wire, are notoriously well-known in the art for their non-sticking characteristics. More specifically, Teflon is known as "a waxy, opaque material, polytetrafluoroethylene, employed as a coating...to prevent sticking." *The American Heritage Dictionary of the English Language*, Fourth Edition 2000. Similarly, silicone is "characterized by ...high lubricity, extreme water repellence and physical inertness..." *The American Heritage Dictionary of the English Language*, Fourth Edition 2000.

In the Office Action, it is asserted that the Patent to Nicholson *et al.* discloses a means (marker/indicia) to measure a quality of the ductal fluid *in situ*. However, no such description appears in the Patent to Nicholson *et al.*

In the Patent to Nicholson *et al.*, the probe wire (12) is a solid structure composed of titanium or a bimetal material with no fluid absorbing or molecular binding capabilities.

Nevertheless, it appears that the position has been taken in the Office Action that the Graduations (26) provided on the proximal extent of the probe wire are a means to measure the quality of ductal fluid *in situ* (see Office Action page 3). As stated in the Patent to Nicholson *et al.*, the graduations "...indicate both the depth of the probe's wire distal end when anchored and the depth of the probe unit's distal ends when the wire is properly sheathed in the cannula (see col. 4, lines 13-16). Therefore, the Patent to Nicholson *et al.* does not disclose a device capable of measuring the quality of ductal fluid *in situ*, much less a device cable of retrieving a sample of breast duct fluid from within a breast duct for analysis.

Further, insertion of the wire into a breast duct through a ductal orifice is not disclosed or contemplated in the patent to Nicholson *et al.* First, the shape of the probe wire with its hook does not allow for insertion into a breast duct through a ductal orifice, at least because of the size of the hook relative to a ductal opening. Second, the wire's percutaneous tip, if inserted within a breast duct, could puncture the duct thereby causing it to collapse and causing significant injury to the patient. A person of ordinary skill in the art would recognize the serious potential for injury of a patient by placing a puncturing device, such as the wire of Nicholson *et al.*, in a breast duct of a body. For all of the above discussed reasons, the Patent to Nicholson *et al.* does not disclose the recited device. Additionally, it would not have been obvious to one of ordinary skill in the art to modify the percutaneously tipped hooked wire of Nicholson *et al.* so that it could receive a ductal fluid sample because no motivation exists for such a modification and such a modification is contrary to the common knowledge of the ordinary artisan.

As mentioned previously, the Patent to Pestes *et al.* does not disclose a probe having a diameter sized to penetrate a breast duct, rather it discloses only a much larger device for insertion into an urethra. As a result, the Applicant asserts that a prima facie case of anticipation has not been set forth because the device disclosed in the Patent to Pestes *et al.* is not sized to

penetrate a breast duct through a ductal orifice, pass through the sphincter, contact an interior lumen of a breast duct, and retrieve a sample of the breast duct fluid.

Thus, Applicant submits that neither the Patent to Pestes *et al.*, nor the Patent to Nicholson *et al.* either alone or in combination, anticipates the claimed subject matter of the present invention.

CONCLUSION

For all of the above-discussed reasons, Applicant respectfully submits that claims 1-13, 26 and 27 are allowable and that the application is now in condition for allowance. A notice to this effect is earnestly solicited. It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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